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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,764	03/29/2006	Menghang Xia	21421P	2257
210	7590	11/13/2008	EXAMINER	
MERCK AND CO., INC			DANG, IAN D	
P O BOX 2000			ART UNIT	
RAHWAY, NJ 07065-0907			PAPER NUMBER	
			1647	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/573,764	XIA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-9,15-21,31,32,36-38,43,45 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,3-5,7-9,15-21,31,32,36-38,43,45 and 47-50 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> .  |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 29 March 2006 has been entered in full. Claims 2, 6, 10-14, 22-30, 33-35, 39-42, 44, and 46 have been cancelled and claims 8, 16, 32, and 47 have been amended.

Claims 1, 3-5, 7-9, 15-21, 31, 32, 36-38, 43, 45, 47-50 are pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 7-9, 15, and 45 drawn to an isolated nucleic acid molecule of an alternative splicing variant of a human T-type calcium channel subunit, an expression vector comprising the nucleic acid, a recombinant host cell, and a recombinant human cell line which has been engineered to express a heterologous protein.

Group II, claim(s) 3-5, drawn to a substantially pure polypeptide comprising an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO:18 or 20 or an amino acid sequence encoded by SEQ ID NO:19 or 21.

Group III, claim(s) 16-18, drawn to a method of identifying candidate compounds capable of binding to the polypeptide human T-type calcium channel subunit and modulating its activity.

Group IV, claim(s) 19-21, drawn to a method of detecting an  $\alpha_{1I}$  isoform in a first biological sample.

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Group V, claim(s) 31-32, drawn to a method for treating a subject having a stroke, epileptic seizure, or traumatic brain injury comprising administering to a subject an inhibitor of the human T-type calcium channel  $\alpha_{1L-1}$  subunit.

Group VI, claim(s) 36-37, drawn to a method for identifying lead compounds for a pharmacological agent useful in the treatment of disease associated with increased or decrease voltage regulated calcium influx mediated by a human T-type calcium channel.

Group VII, claim(s) 38, drawn to a method for identifying compounds which selectively bind a human T-type calcium channel  $\alpha_{1L-1}$  subunit isoform.

Group VIII, claim(s) 43, drawn to an isolated antibody which specifically binds to a polypeptide comprising an amino acid sequence of SEQ ID NO:19 or SEQ ID NO:21.

Group IX, claim(s) 47, drawn to a method of producing the recombinant protein.

Group X, claim(s) 48-50, drawn to a method of identifying compounds that modulate the activity of T-type calcium channel  $\alpha_{1L-1}$  subunit.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-X do not relate to a single general inventive concept because they lack the same or corresponding technical feature.

Claim 1 is drawn to an isolated nucleic acid molecule of an alternative splicing variant of a human T-type calcium channel subunit. Venter et al. (WO 02/068579 A2; filed 01/10/2002; published 09/06/2002) teach an isolated nucleic acid molecule of SEQ ID NO:16356 that encodes biological fragments with a 76.4% homology to the nucleic acid of SEQ ID NO:18 encoding a polypeptide capable of forming a function T-type calcium channel (see alignment in

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Exhibit A), since the protein is 100% identical over the fragment spanning nucleic acids 3679 to 5838 it would be expected in absence of evidence to the contrary. The prior art meets the limitations disclosed in claim 1. Thus Group I lacks novelty or inventive step and does not make a contribution over the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

Under PCR Rule 13.1, the application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

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examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
November 6, 2008

/Robert Landsman/  
Primary Examiner, Art Unit 1647